UNTIED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

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| In Re: | ) | |
| AREDIA and ZOMETA PRODUCTS LIABILITY LITIGATION | ) | No. 3:06-MDL-01760<br>Judge Campbell/Brown |
| Related to Case No. 3:06-cv-01166 | ) | |

**TO: The Honorable Todd J. Campbell**

**REPORT AND RECOMMENDATION**

## I. INTRODUCTION

Plaintiffs, Francine Scalamoni, Joseph Scalamoni, George Davis and Helen Davis (hereinafter "Plaintiffs") have filed a Consolidated Motion and Memorandum of Law for Remand and Attorney's Fees After Improvident Removal (Case No. 3:06-1166, Docket Entry 15, Exhibit 7). This Consolidated Motion was referred to the undersigned for Report and Recommendation. (Case No. 3:06-MDL-1760, Docket Entry 217).

For the reasons stated below, the Magistrate Judge **recommends** that the Plaintiffs' Consolidated Motion for Remand be **GRANTED** and that Plaintiffs' causes of action be **REMANDED** to New Jersey state court. Further, the Magistrate Judge **recommends** that Plaintiffs' request for attorneys' fees be **DENIED**.

## II. BACKGROUND

Plaintiffs are residents of New Jersey. (Case No. 3:06-1166, Docket Entry 15, Exhibit 4, Page 2, ¶¶ 2-5). Defendant is a corporation incorporated in Delaware with its principal offices

located in New Jersey. (Case No. 3:06-1166, Docket Entry 15, Exhibit 2, Page 2, ¶ 6). The complaint was filed on August 25, 2006, in the Superior Court of New Jersey. (Case No. 3:06-1116, Docket Entry 15, Exhibit 4). The complaint alleges that Plaintiffs' developed severe osteonecrosis of the jaw (hereinafter "ONJ") caused by their use of the drug Aredia© and/or the drug Zometa© (hereinafter "the medications"). Plaintiffs request both compensatory and punitive damages under the New Jersey Products Liability Act as well as under common law theories of strict liability, negligence, breach of warranty (express and implied) and loss of consortium. In Count IV, Plaintiffs allege that Defendant negligently failed to warn Plaintiffs and their medical providers of the risks involved in using the medications. Additionally, Plaintiffs allege that Defendant failed to meet the standard of care set by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et. seq (hereinafter "FDCA"), regarding labeling. Plaintiffs contend that the labeling lacked adequate information on the use of the drugs, failed to provide adequate warnings regarding the use of the drugs, was misleading and promotional. Further, Plaintiffs contend that Defendant's acts above constitute an adulteration and/or misbranding as defined by FDCA § 331. Specifically, paragraph 45 alleges that:

> As a result of Defendant's negligence and the violations of the statutes and regulations listed above[1], Plaintiffs suffered injuries and damages as alleged herein. As a direct and proximate result of Defendant's failure to warn, Plaintiff's have developed osteonecrosis of the jaw, are at risk of developing other diseases, and have suffered compensatory damages and are entitled to punitive damages in the amounts to be proven at trial.

Defendant filed a timely petition for removal from the state court to the United States

[1]In addition to 21 U.S.C. §331, Plaintiffs allege that Defendant violated the Sherman Food, Drug and Cosmetic Law and the following federal statutes regarding the labeling issues described above: 21 C.F.R Section 201.26(a), (b) and (d), 21 C.F.R. 201.57(e) and (f)(1) and (2). (Case No. 3:06-1166, Docket Entry 15, Exhibit 4, Page 11, ¶42).

District Court of New Jersey alleging that the Court has federal question jurisdiction under 28 U.S.C. § 1331.[2] (Case No. 3:06-1166, Docket Entry 15, Exhibit 3). To support the removal, Defendant propounded three arguments. First, citing *Grable & Sons Metal Prods., Inc. V. Darue Eng'g & Mfg*,[3] Defendant advanced that Plaintiffs' claims require resolution of substantial federal issues, even though a federal cause of action is not directly listed in the complaint, because Plaintiffs allege that the FDA-approved labeling of the medications was inadequate, false and misleading and that the medications were not adequately tested. Second, Defendant puts forth that the Court has federal question jurisdiction under the doctrine of complete preemption because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medications that any challenge to such marketing and promotion necessarily states a federal cause of action: violation of the FDCA and its implementing regulations." Third, and lastly, Defendant argues that Plaintiffs' claim for punitive damages also raises a substantial federal question because New Jersey's product liability punitive damages statute incorporates federal law by providing for a fraud-on-the-FDA prerequisite.[4]

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[2]Interestingly enough, there are still several cases pending against the Defendant involving these specific medications which are currently pending in New Jersey state court. Therefore, to some extent, the argument about remand of this one case is a bit of a tempest in a teapot.

[3]545 U.S. 308, 125 S.Ct. 2363, 2366-67 (2005). Additionally, Defendant cites an FDA memorandum regarding the approval of product labeling, conflicting state law claims related to the adequacy of prescription drug warnings, and preemption arguments. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3934, 39935 (Jan. 24, 2006).

[4]N.J.S.T. § 2A:58C-5 which states:

> Punitive damages shall not be awarded if a drug or device or food or food additive which cause the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug and Cosmetic Act," 52

Plaintiffs filed the instant motion to remand to the state forum on the ground that federal court lacks subject matter jurisdiction as each of the Plaintiffs' seven claims in their well pleaded complaint are based on state statutory or common law. (Case No. 3:06-1166, Docket Entry 15, Exhibit 7). Further, Plaintiffs request their attorneys' fees and costs. Shortly after filing the instant motion and subsequent response and reply, this case was transferred to this District for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. (Case No. 3:06-1166, Docket Entry 15, Exhibit 16). It appears that neither party objected to the transfer.

## III. LEGAL DISCUSSION[5]

Only state actions that originally could have been filed in federal court may be removed to the federal court by the defendant. 28 U.S.C. § 1441. The party removing the case to federal court bears the burden of proving that the federal court has jurisdiction. *Id*. The question of whether a claim "arises under" federal law must be determined by reference to the "well-pleaded complaint" rule, examining the well pleaded allegations of the complaint and ignoring potential defenses. 28 U.S.C. §§ 1331, 1441; *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d 318, 322 (6th Cir. 2005). The well-pleaded complaint rule recognizes that the plaintiff is the master of his complaint. *Id*. Accordingly, if the plaintiff chooses to bring a state law claim, that claim cannot

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> Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

[5]The Magistrate Judge stresses to both parties the well known concept that less is more. The superfluous citing of cases that only marginally advance arguments is unnecessary as is the continuous repetition of the same arguments.

generally be "recharacterized" as a federal claim for purposes of removal. *Id*. However, while this rule makes the plaintiff the master of his claim, the plaintiff may not avoid federal jurisdiction by omitting from the complaint allegations of federal law that are essential to the claim. If the plaintiff does so, a court may recharacterize the "artfully-pleaded" complaint as though it had been "well-pleaded."

One narrow exception to the well-pleaded complaint rule is the doctrine of "complete preemption."[6] This doctrine permits removal of an action to federal court when a federal statute wholly displaces a state law cause of action. *Strong v. Teletronics Pacing Sys., Inc.*, 78 F.3d 256 (6th Cir. 1996).

Another relatively new, and equally limited, exception to the well-pleaded complaint rule is substantial federal issue preemption. The Supreme Court has recently held that there is federal question jurisdiction, even in the absence of an express or implied federal cause of action, if a substantial federal question of great federal interest is raised by a complaint framed in terms of state law, and if resolution of that federal question is necessary to the resolution of that state-law claim. *Merrell Dow Pharmaceuticals, Inc., v. Thompson*, 478 U.S. 804, 106 S.Ct. 3229 (1986); *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 125 S.Ct. 2363 (2005).

**A. Whether there is complete preemption**

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[6]The Supreme Court has demonstrated a reluctance to extend the application of the "complete preemption" exception. See *Palkow v. CSX Transp., Inc.*, 431 F.3d 543, 553-54 (2005), for a detailed account of when the Supreme Court has applied this very limited exception, mainly for those claims involving LMRA and ERISA as well as usury and copyright laws.

As the party invoking removal, and since the face of the Plaintiff's well-pleaded complaint does not state a federal claim, the Defendant bears the burden of establishing Plaintiffs' cause of action is completely preempted. Defendant asserted in it's Notice of Removal that this Court has jurisdiction under the doctrine of complete preemption because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medication that any challenge to such marketing and promotion necessarily states a federal cause of action: violation of the FDCA and its implementing regulations." (Case No. 3:06-1166, Docket Entry 15, Exhibit 3, ¶¶ 7,8, and 9).[7] Plaintiffs responded in their Motion for Remand as well as in their reply brief that the complete preemption doctrine simply does not apply and that Defendant has cited no authority for this assertion. (Case No. 3:06-1116, Docket Entry 15, Exhibit 14, Page 9-10, 12-13).

The Magistrate Judge agrees with the Plaintiffs. The Defendant confusingly blurs it's arguments regarding complete preemption which warrants removal with those of ordinary preemption of state law. Complete preemption that supports removal and ordinary preemption are two distinct concepts. *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d at 323 (citing 28 U.S.C. § 1441 and *Warner v. Ford Motor Co.*, 46 F.3d 531, 535 (6th Cir. 1995)(en banc)). Complete preemption that permits removal is reserved for statutes designed to occupy the regulatory field with respect to a particular subject *and to create a superseding cause of action*, while ordinary preemption applies to statutory sections that arguably supersede conflicting state

[7]It should be noted that the Defendant did not advance it's complete preemption argument in it's Opposition to the instant Motion to Remand or during the January 22, 2007, hearing. However, given that it was originally one prong of Defendant's basis from removal, it is fully addressed in this Report and Recommendation.

law. *Id*. (emphasis added). "In other words, the complete preemption doctrine is not simply one of preemption of the law, it is a sort of 'super' preemption which preempts not only the state law, but also creates federal jurisdiction-to use the jargon of the day, it is 'preemption on steroids.'" *Palkow v. CSX Transp., Inc.*, 431 F.3d 543, 553 (6th Cir. 2005). Additionally, it is important to note that a case may not be removed to federal court on a the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 107 S.Ct. 2425 (1987); *Baldwin v. Pirelli Armstrong Tire Corp.*, 927 F.Supp. 1046 (M.D. Tenn. 1996).

It is now clear to the Magistrate Judge that the Defendant's arguments, while arguably supporting ordinary preemption of Plaintiffs' state law claims and/or federal question jurisdiction under substantial federal question preemption as discussed in detail below, do not support a finding of complete preemption. "The congressional intent necessary to confer removal jurisdiction upon the federal district courts through complete preemption is expressed through creation of a parallel federal cause of action that would 'convert' a state cause of action into the federal action for purpose of the well-pleaded complaint rule." *Strong v. Teletronics Pacing Sys., Inc.*, 78 F.3d at 260; *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d 318 (6th Cir. 2005). When Congress has indicated an intent to so completely occupy the field, any ostensibly state law claim is in fact a federal claim for purposes of arising-under jurisdiction. *Id*. Applying the standard to the instant matter, complete preemption does not apply as the FDCA does not create or imply a private right of action for individuals injured as a result of the violations of the

Act.[8]

Given the limited number of statutes which the Supreme Court has found to "completely preempt" state law claims so as to permit recharacterization of a plaintiffs' claim as a federal claim so that removal is proper, as well as the Defendant's failure to cite to and the Magistrate Judge's inability to locate any cases which hold that labeling based claims under the FDCA are completely preempted, it is apparent that complete preemption should not be applied in the instant case. The fact that the Defendant might ultimately prove that Plaintiffs' claims are preempted under the FDCA does not establish that such state law based claims are now removable to federal court. See *Caterpillar*, 482 U.S. at 398.

**B. Whether Plaintiffs' claims require the resolution of substantial federal issues**

The Defendant also argues that federal question jurisdiction exists to support removal under the contours of 28 U.S.C. § 1331, as interpreted by recent Supreme Court holdings, which carve out a new, non-complete preemption form of federal question jurisdiction for purposes of removal of state law claims. *Palkow*, 431 F.3d at 554 (citing *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986)). The Supreme Court now allows for federal jurisdiction if there is a substantial federal issue raised by a state action based complaint, if resolution of that

[8]Defendant has apparently made a similar arguments regarding misbranding and other labeling issues in previous litigation involving the use of the drug Elidel. *Perry v. Novartis Pharma. Corp.*, 456 F.Supp.2d 678 (E.D. PA 2006). The Magistrate Judge notes that *Perry* was a diversity action and did not deal with the issue of remand. However, the FDCA conflict preemption analysis is still useful. Specifically, the Court found that, ". . .the bar to a finding of preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus, a finding of preemption here will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Courts have (understandably) been particularly reluctant to find preemption in such cases without an unambiguous signal of Congressional intent. Courts should therefore not reach to find that FDA regulations preempt state law claims." *Id*. at 684.

federal issue is necessary to the resolution of that state-law claim. *Merrell Dow*, 478 U.S. at 804; see also *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 125 S.Ct. 2363 (2005).

The Defendant argues that there are two main substantial federal issues raised by the Plaintiffs' state action based complaint that warrant federal jurisdiction: (1) Plaintiffs' references in the Complaint in Count IV (Negligence–Failure to Warn) to the Defendant's alleged violation of the FDCA regarding warnings and labeling[9] and (2) the Plaintiffs' claims for punitive damages which Defendant argues requires the Plaintiffs to prove "fraud on the FDA" as a prerequisite to recovery. Plaintiffs respond that all causes of action are based solely upon state law and do not require that they prove the Defendant violated any portion of federal law as an element of, or prerequisite to, any of their claims. Plaintiffs further respond that even if federal issues are involved, such issues are not substantial to an extent that they warrant federal jurisdiction. Again, the Magistrate Judge agrees with the Plaintiffs that their state based action does not warrant federal jurisdiction.

**1. Count IV (Negligence–Failure to Warn)**

Similar to the instant case, the Supreme Court, in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, found that a state court negligence action against a drug manufacturer resting in part on the allegation that the defendant drug company had violated a federal misbranding prohibition did not present a federal question, so that removal of the action to federal court was improper. 478 U.S. 804 (1986). The Supreme Court held that "a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should

[9]The Defendant cites a laundry list of possible federal issues related to this issue. (Case No. 06-1166, Docket Entry 15, Exhibit 11, Pages 11-12).

be no private, federal cause of action for the violation, does not state a claim 'arising under'" §1331. *Id*. at 817. In short, Congress did not intend a private federal remedy for violations of the statute [the FDCA] that it enacted and therefore, the presence of a federal issue as an element of the state tort claim is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system. *Id*. at 814. The Supreme Court found, even assuming that federal law would have to be applied to resolve the claim, that federal jurisdiction was unavailable after closely examining the strength of the federal issue at stake and the implications of opening the federal forum. *Id*. at 817.

The Supreme Court further clarified *Merrell Dow* in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005). The Court stated that *Merrell Dow* could not be read to make a federal cause of action created by Congress a necessary condition for federal question jurisdiction.[10] Specifically, the Court reiterated that *Merrell Dow* "should be read in its entirety as treating the absence of such cause as evidence relevant to, but not dispositive of, the 'sensitive judgements about congressional intent' required by § 1331." *Id*. at 309 (citing *Merrell Dow v. Thompson*, 478 U.S. at 810). The Court stated that while it could not state a "single, precise, all embracing" test for jurisdiction over federal issues embedded in state-law claims between non-diverse parties, the question to ask is:

> Does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities?

The Court further detailed that in such cases, "federal jurisdiction demands not only a contested

[10]There was an apparent split between the circuits on whether the holding in *Merrell Dow* meant there must always be a federal cause of action as a condition for exercising federal-question jurisdiction. The Supreme Court in *Grable*, as described above, resolved this issue.

federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." *Id*. at 313. Additionally, because arising -under jurisdiction always raises the possibility of upsetting the division of labor between the state and federal courts, even when the state action raises a contested and substantial federal issue, this issue will only qualify for federal jurisdiction if it is "consistent with congressional judgment" on the proper division of labor between the two court systems. *Id.* The Court concluded stating that Merrell Dow's "analysis thus fits within the framework of examining the importance of having a federal forum for the issue, and the consistency of such a forum with Congress's intended division of labor between state and federal courts." Id. at 319.

In *Merrell Dow*, the Court held that a general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would have "heralded a potentially enormous shift of traditionally state cases into federal courts." *Grable v. Darue*, 545 U.S. at 319 (citing *Merrell Dow v. Thompson*, at 811-812). In *Grable*, the Court upheld this portion of it's decision in *Merrell Dow* stating: "For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases." *Id*. at 318.

The standards set by both *Merrell Dow* and *Grable* purposefully do not set clear jurisdictional boundaries. Rather, the Supreme Court has made it clear that each case involving an alleged violation of the FDCA must be reviewed to determine whether it should be distinguished on its facts from those in *Grable* and *Merrell Dow*. In the instant case, given the significance of the assumed Congressional preclusion of federal private remedies for

misbranding under the FDCA as well as the "potentially enormous shift of traditionally state cases into federal courts," the Magistrate Judge finds any possible federal issues related to Plaintiffs' failure to warn claims, as alleged and described by both the Plaintiffs and the Defendant, do not rise to the kind of adjudication for which federal jurisdiction would serve congressional purposes and the federal system. *Grable v. Darue*, 545 U.S. at 319 (citing *Merrell Dow v. Thompson*, at 811-812). While the Magistrate Judge has reviewed the Defendant's list of *potential* federal issues,[11] given the Supreme Court's holdings in *Grable* and *Merrell Dow*, these are not substantial to the extent that the Plaintiffs' case rests on the resolution of these issues. In spite of Defendant's blanket assertions to the contrary, Plaintiffs' stated causes of action do not require proof of violation of federal law as an essential element to recovery.[12] *Grable v. Darue*, 478 U.S. at 814. The Magistrate Judge believes these issues, if they arise, could be properly handled by the state court as part of Plaintiffs' state law claims.[13]

Further, the Defendant argues at length that the novelty of these issues, especially in light

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[11] Case No. 3:06-cv-01166 Docket Entry 15, Exhibit 11, Pages 11-12.

[12] It should also be noted that the Plaintiffs are not requesting that the Defendant modify it's label and related packaging in violation of FDA regulations nor are the Plaintiffs suing the FDA itself in this action.

[13]Interestingly, Defendant has made similar preemptive arguments when requesting a motion to dismiss, again in *Perry v. Novartis Pharmaceuticals Corp.*, 456 F.Supp.2d 678 (E.D. Pa. 2006). The Court rejected Defendant's preemption arguments stating that:

> If at some future date, Congress determines that FDA monitoring is sufficiently effective on its own to warrant the elimination of state law incentives for manufacturers to provide adequate warnings, it also has the authority to declare that failure to warn suits, like the Perry's action, are preempted. Until it does so, however, in the absence of a specific FDA safety determination, such suits can go forward. *Perry*, 456 F.Supp. at 687.

of the recent FDA preamble,[14] justifies the retention of Plaintiffs' labeling based claims.

However, in *Merrell Dow*, the Supreme Court clearly stated that:

> We do not believe the question whether a particular claim arises under federal law depends on the novelty of the federal issue. Although it is true that federal jurisdiction cannot be based on a frivolous or insubstantial federal question, 'the interrelation of federal and state authority and the proper management of the federal judicial system,' would be ill served by a rule that made the existence of federal-question jurisdiction depend on the district court's case-by-case appraisal of the novelty of the federal question asserted as an element of the state tort. The novelty of an FDCA issue is not sufficient to give it status as a federal cause of action; nor should it be sufficient to give a state-based FDCA claim status as a jurisdiction-triggering federal question. 478 U.S. at 817 (citing *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 8 (1983).

Therefore, the novelty of any possible federal issues presented by the Defendant is clearly not sufficient to establish federal question jurisdiction.

**2. Plaintiffs' claims for punitive damages**

A more interesting argument is made by the Defendant related to Plaintiffs' punitive damages claims. However, while the Magistrate Judge agrees with the Defendant that state courts cannot step into the shoes of the FDA to determine whether a fraud on the FDA has been committed, Plaintiffs' claims for punitive damages still do not warrant federal jurisdiction, for reasons discussed in detail below.

The relevant portion of N.J. Stat. Ann. § 2A:58C-5(c) states: ". . .where the product manufacturer knowingly withheld or misrepresented information required to be submitted under

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[14]The *Perry* Court, in response to Defendant's reliance on the non-binding authority of the recent FDA preamble which arguably takes the position that its labeling requirements should have a preemptive effect (71 Fed. Reg. 3922 (Jan. 24, 2006)), persuasively stated that Congress, not federal agencies, have the power to preempt state law claims as "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Perry*, at 683 (quoting *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). The Magistrate Judge agrees with the *Perry* Court's analysis on the deference to the FDA's preamble and advisory opinions and therefore, need not repeat it here at length. See *Perry*, 456 F.Supp. at 682-84.

the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded."[15]

The Defendant makes the argument that Plaintiffs' claim for punitive damages raises a substantial federal question because New Jersey's punitive damages statute incorporates federal law by providing for a "fraud on the FDA" exception. The Defendant contends that the Plaintiffs are barred from recovering punitive damage unless the Plaintiffs establish the Defendant "knowingly withheld or misrepresented" material and relevant information to the FDA, which would require Plaintiffs to establish that the Defendant violated federal law in its submission of materials to the FDA.

Plaintiffs respond that their claims do not turn on a "fraud on the FDA claim," but rather that New Jersey law sets a standard where a plaintiff need only show that the drug company withheld information that was material and relevant to the harm in question in order to support a punitive damages claim. Plaintiffs assert that no inquiry into FDA procedures or analysis or speculation as to what the FDA would have done with the information is necessary.

The Supreme Court has expressly considered the question of a state common law fraud-on-the-FDA tort claim and has found that it is impliedly preempted by the FDCA. *Buckman Company v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001). *Buckman* was a diversity case where the plaintiffs' theory of liability was that but-for the defendant's fraudulent statements to the FDA, the bone screws would have never received FDA approval, and the plaintiffs would not have been injured. 531 U.S. 341 (2001). The Supreme Court found that, "Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id*. at 347

[15]For the statute's full text, see footnote 4.

(citing *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218 (1947)). Further, the Supreme Court found that state law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgement and objectives. *Id*. at 350. The Supreme Court was concerned that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA..." *Id*. Further, fraud-on-the-FDA claims "would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants or needs, resulting in additional burdens on the FDA's evaluation of an application" causing delays and impeding competition. *Id*. at 351.

In contrast to *Buckman*, the present case does not involve a claim of fraud-on-the-FDA but instead involves a state statute which immunizes drug manufacturers from punitive damage liability *unless* the plaintiff can prove fraud on the FDA. Stated differently, *Buckman* involved a specific cause of action for fraud on the FDA, whereas the instant Plaintiffs must prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under New Jersey law.

It appears that two other courts have considered this very same issue. In *Garcia v. Wyeth-Ayerst*, a diversity action, the plaintiff brought a products liability action against a drug manufacturer seeking punitive damages. 385 F.3d 961 (2004). Michigan, like New Jersey, immunizes drug manufacturers from punitive damage liability in actions based on injuries from FDA-approved drugs absent a showing that the drug manufacturers secured FDA approval through fraud. The Sixth Circuit held that the distinction between a plaintiff who brought a

direct cause of action for fraud on the FDA and a plaintiff who had to prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under Michigan law was immaterial in light of *Buckman*. *Id*. at 965-66. The Sixth Circuit held that regardless of whether a plaintiff is required to prove fraud on the FDA as a cause of action unto itself or simply as a prerequisite in a punitive damages action, "such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id*. at 966 (citing *Buckman*, 531 U.S. at 351).

The Sixth Circuit did find that the Michigan law fraud exceptions, under *Buckman*, could be applied in certain situations. "Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of a *state court* findings of fraud on the FDA....[however those concerns stated in *Buckman*] do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id*. at 966. "Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into the law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings (e.g, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (e.g. claims based on federal findings of bribery or fraud on the FDA)." *Id*. Therefore, the Sixth Circuit found that the Michigan law did not conflict with the FDCA as long as the proof of the fraud-on-the-FDA element was satisfied only by a finding by the FDA itself that it had been defrauded. *Id*. at 966.[16] The Sixth Circuit concluded that absent such a finding by the FDA, the statute was unconstitutional but severable, placing "responsibility for

[16]This is supported in *Buckman* by Justice Stevens, concurring: "If the FDA determines both that fraud has occurred and that such fraud requires the removal of products from the market, state damage remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." 531 U.S. at 354.

prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts." *Id*. at 967.

In *Kobar v. Novartis Corporation*, the same issue was presented as in *Garcia*, in the context of a similar Arizona statute, on a motion for partial summary judgment on the issue of punitive damages. 378 F.Supp.2d 1166 (2005). There, the Plaintiff made the same argument as the Plaintiffs in the instant case, i.e. that she did not have to prove fraud on the FDA but rather merely that the drug manufacturer withheld "material and relevant" information from the FDA during the approval process. *Id*. at 1172-73. However, the *Kobar* Court was not persuaded by the distinction finding that: "Both common law fraud on the FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process." *Id*. The *Kobar* Court further stated that the "FDA is equally empowered to police and deter fraud with respect to the drug approval process. . .[and] the FDA has the authority to request additional information from a drug manufacturer, investigate suspected fraud, seek injunctive relief and civil penalties and pursue criminal prosecutions." *Id*. at 1173. As in *Garcia*, the *Kobar* Court found that severing the fraud exceptions from the rest of the Arizona statute would still allow a plaintiff to obtain punitive damages so long as the FDA itself made a finding that it has been defrauded by the drug manufacturer. *Id*. at 1176. Also as in *Garcia*, the *Kobar* Court found that the statute was unconstitutional in all situations except when the FDA makes a finding that it has been defrauded. *Id*. at 1174-75.[17]

[17]The Second Circuit, interpreting the same Michigan law, has disagreed with the Sixth Circuit's holding in *Garcia*. In *Desiano v. Warner-Lambert & Co.*, the Second Circuit found

Neither *Buckman, Garcia* or *Kobar* address whether the request for punitive damages when there is a fraud-on-the-FDA exception is a substantial issue which warrants removal to federal court. Therefore, this is a novel issue presented to this Court. At this point, the Magistrate Judge goes back to the standard set by the Supreme Court in *Grable*:

> Does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities? 545 U.S. at 313.

Further, it is important to again note that a case may not be removed to federal court on a the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 107 S.Ct. 2425 (1987). *Baldwin v. Pirelli Armstrong Tire Corp.*, 927 F.Supp. 1046 (M.D. Tenn. 1996).

Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. The object of the New Jersey

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that federal law did not preempt the punitive damages immunity exception. 467 F.3d 85 (2nd Cir. 2006). The Second Circuit advanced that the immunity granted by the Michigan statute was in the form of an affirmative defense for drug manufacturers regarding punitive damage liability and that,

> "Finding preemption of traditional common law claims where fraud is not even a required element–but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law–would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." *Id*. at 96.

The Magistrate Judge respectfully disagrees with the Second Circuit's interpretation of the Michigan statute which provides drug manufacturer's, not with an affirmative defense, but with absolutely immunity regarding punitive damages absent a showing that the drug manufacturer secured FDA approval through fraud. For the reasons clearly outlined above, the Magistrate Judge believes that the FDA itself must make this finding of fraud.

legislature in creating this statute was to regulate and restrict when Plaintiffs could recover punitive damages, which falls squarely within its prerogative to regulate matters of health and safety. Where Plaintiffs seek punitive damages under the New Jersey statute in either state or federal courts and the issue on fraud-on-the-FDA is raised, the potential would exist for the FDA's personnel to be drawn into those controversy on a case-by-case basis over and over again. This would generate a wholly impractical situation. Therefore, the Magistrate Judge believes that, in the instant case, the Plaintiffs, whether in federal or state court, will not be entitled to punitive damages absent a finding *by the FDA* that the Defendant committed fraud on the agency. The concerns expressed in *Buckman, Garcia* and *Kobar*, such as state courts having to step into the shoes of the FDA in making fraud determinations and the possible delay in the drug approval if applicants feared that their disclosures to the FDA although deemed appropriate by the Administration will later be judged insufficient in state courts, are also equally true if federal courts, on a federal district by federal district or even federal circuit by federal circuit, make determinations of fraud. As such, whether in federal or state court, the FDA will need to make a finding on the matter of fraud before the Plaintiffs will be entitled to recover punitive damages under New Jersey law.

With all of this said, it is the Magistrate Judge's belief that Plaintiffs' claims for punitive damages will not require the New Jersey state court to find fraud-on-the-FDA and as such, no substantial federal issue is present which warrants federal jurisdiction. Rather, the Defendant will have to present a defense to the New Jersey state court, similar to the Defendants in *Garcia* and *Kobar*, that the portion of the New Jersey statute which requires Plaintiffs to demonstrate that "the product manufacturer knowingly withheld or misrepresented information required to be

submitted under the agency's regulations, which information was material and relevant to the harm in question" is preempted and can only be satisfied by an FDA finding of fraud. As noted above, this federal preemption defense is not sufficient to remove a state law complaint to federal court.

In summary, the Magistrate Judge believes that the Plaintiffs will be required to submit a finding by the FDA of fraud prior to being able to recover punitive damages in either state court or in federal court. While this specific issue preemption argument has not been presented in regards to the New Jersey statute in question, the Defendant can present such an argument as a defense in state court if needed. As such, there is no substantial issue presented regarding punitive damages which warrants federal jurisdiction.

**C. Whether Plaintiffs are entitled to attorneys' fees**

The Magistrate Judge believes that the Defendant had an objectively reasonable basis for seeking removal, when considering the combined effect of all of it's arguments regarding labeling as well as it's novel argument regarding punitive damages. Therefore, the Plaintiffs are not entitled to their attorneys' fees and costs incurred as a result of the removal. 28 U.S.C. § 1447(c).

## IV. RECOMMENDATION

For the reasons stated above, the Magistrate Judge **recommends** that the Plaintiffs' Consolidated Motion for Remand be **GRANTED** and that Plaintiffs' causes of action be **REMANDED** to New Jersey state court. Further, the Magistrate Judge **recommends** that Plaintiffs' request for attorneys' fees be **DENIED**.

Under Rule 72(b) of the Federal Rules of Civil Procedure, any party has ten (10) days

from receipt of this Report and Recommendation in which to file any written objections to this Recommendation, with the District Court. Any party opposing said objections shall have ten (10) days from receipt of any objections filed in this Report in which to file any responses to said objections. Failure to file specific objections within ten (10) days of receipt of this Report and Recommendation can constitute a waiver of further appeal of this Recommendation. Thomas v. Arn, 474 U.S. 140, 106 S.Ct. 466, 88 L.Ed.2d 435 (1985), reh'g denied, 474 U.S. 1111 (1986).

**ENTERED** this 2nd day of February, 2007.

/S/ Joe B. Brown
JOE B. BROWN
United States Magistrate Judge